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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Omry Ben-Ezra, et al.
U.S. Serial No. : 10/560,654
Filed : May 1, 2006
For : VAGAL STIMULATION FOR ANTI-EMBOLIC
THERAPY

1185 Avenue of the Americas
New York, New York 10036
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ATTN: GROUP ART UNIT 3762
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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

In order to ensure compliance with applicants' duty of disclosure under 37 C.F.R. §1.56 and §1.97(a)-(d), applicants request that the following documents be considered and made of record in the above-identified application which is listed on Form PTO-1449, attached hereto as **Exhibit A**.

1. Bibevski, S. and Dunlap M.E., (1999) "Ganglionic Mechanisms Contribute To Diminished Vagal Control In Heart Failure," *Circulation*, 99(22):2958-63 (**Exhibit 1**);
2. Bilgutay, A.M. et al., (1968) "Vagal Tuning. A New Concept In The Treatment Of Supreantricular Arrhythmia, Angina Pectoris, And Heart Failure," *The Journal of Thoracic and Cardiovascular Surgery*, 56(1): 71-82 (**Exhibit 2**);

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3. Bluemel, K.M. et al., (1990) "Parasympathetic Postganglionic Pathways To the Sinoatrial Node," *The American Journal of Physiology*, 259(5 Pt 2):H1504-10 **(Exhibit 3)**;
4. Carlson, M.D. et al., (1992) "Selective Stimulation Of Parasympathetic Nerve Fibers To The Human Sinoatrial Node," *Circulation*, 85: 1311-1317 **(Exhibit 4)**;
5. Chen, S. et al., (1998) "Intracardiac Stimulation Of Human Parasympathetic Nerve Fibers Induces Negative Dromotropic Effects: Implication With The Lesions Of Radiofrequency Catheter Ablation," *Journal of Cardiovascular Electrophysiology*, 9(3): 245-52 **(Exhibit 5)**;
6. Cooper, T.B. et al., (1980) "Neural Effects On Sinus Rate And Atrioventricular Conduction Produced By Electrical Stimulation From A Transvenous Electrode Catheter In The Canine Right Pulmonary Artery," *Circulation Research*, 46: 48-57 **(Exhibit 6)**;
7. Cummings, J.E. et al., (1980) "Preservation Of The Anterior Fat Pad Paradoxically Decreases The Incidence Of Postoperative Atrial Fibrillation In Humans," *Journal of the American College of Cardiology*, 43(6): 994-1000 **(Exhibit 7)**;
8. European Application Publication No. EP 0 688 577, published December 27, 1995 (PACESETTER AB) **(Exhibit 8)**;
9. European Application Publication No. EP 0 831 954, published April 1, 1998 (MEDTRONIC INC) **(Exhibit 9)**;

10. Friedrichs, G., (2000) "Experimental Models Of Atrial Fibrillation/Flutter," *Journal of Pharmacological and Toxicological Methods*, 43: 117-123 (**Exhibit 10**);
11. Furukawa, Y. et al., (1989) "Differential Blocking Effects Of Atropine And Gallamine On Negative Chronotropic And Dromotropic Responses To Vagus Stimulation In Anesthetized Dogs," *Journal of Pharmacology And Experimental Therapeutics*, 251(3): 797-802 (**Exhibit 11**);
12. Fuster, V. and Ryden, L.E., (2001) "ACC/AHA/ESC Guidelines For The Management Of Patients With Atrial Fibrillation," *Journal of the American College of Cardiology*, 38(4): 1231-66 (**Exhibit 12**);
13. Garrigue, S. et al., (1998) "Post-ganglionic Vagal Stimulation Of The Atrioventricular Node Reduces Ventricular Rate During Atrial Fibrillation," *Pacing and Clinical Electrophysiology*, 21(4), Part II, 878 (**Exhibit 13**);
14. Goldberger, J.J. et al., (1999) "New Technique For Vagal Nerve Stimulation," *Journal of Neuroscience Methods*, 91(1-2): 109-114 (**Exhibit 14**);
15. Hjalmarson, A., (1999) "Prevention Of Sudden Cardiac Death With Beta Blockers," *Clinical Cardiology*, 22 Suppl 5: V11-5 (**Exhibit 15**);
16. International Application Publication No. WO 01/10375 published February 15, 2001 (IMPULSE DYNAMICS NV, ET AL.) (**Exhibit 16**);

17. International Application Publication No. WO 01/10432
published February 15, 2001 (UAB RESEARCH FOUNDATION)
(Exhibit 17);
18. International Application Publication No. WO 01/26729
A1 published April 19, 2001 (CYBERONICS INC.) (Exhibit
18);
19. International Application Publication No. WO 02/085448
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(Exhibit 20);
21. Kwan, H. et al., (2001) "Cardiovascular Adverse Drug
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24. Mazgalev, T.N., "AV Nodal Physiology," *Hearth Rhythm Society*, www.HRSONline.com (**Exhibit 24**);
25. Page, P.L. et al., (1995) "Regional Distribution Of Atrial Electrical Changes Induced By Stimulation Of Extracardiac And Intracardiac Neural Elements," *The Journal of Thoracic and Cardiovascular Surgery*, 109(2): 377-88 (**Exhibit 25**);
26. Rijkhoff, N.J.M. and Sinkjær, T., (1999) "Selective Stimulation Of Small Diameter Nerve Fibers In A Mixed Bundle," *Proceedings Of The Annual Project Meeting Sensations/Neuros And Mid Term Review Meeting Neuros*, p. 20-21 (**Exhibit 26**);
27. U.S. Application Publication No. 2002/0035335 published March 21, 2002 (Shauerte, P.);
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31. U.S. Application Publication No. 2003/0040774 published September 16, 2003 (Terry, R. et al.);
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34. U.S. Application Publication No. 2003/0078623 published April 24, 2003 (Weinberg, L. et al.);
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37. U.S. Application Publication No. 2003/0216775 published June 6, 2006 (Hill, M. et al.);
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41. U.S. Application Publication No. 2004/0048795 published March 11, 2004 (Ivanova, S. et al.);
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43. U.S. Application Publication No. 2004/0138721 published July 15, 2004 (Osorio, et al.);
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60. U.S. Patent No. 3,411,507 issued November 19, 1968 to Wingrove;
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153. U.S. Patent No. 6,272,377 issued August 7, 2001 to Sweeney, R.J. et al.;
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167. U.S. Patent No. US 6,493,585 issued December 10, 2002 to Plicchi, G. et al.;
168. U.S. Patent No. US 6,511,500 issued January 28, 2003 to Rahme, M.;
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173. U.S. Patent No. 6,610,713 issued August 26, 2003 to Tracey, K.;
174. U.S. Patent No. 6,628,987 issued September 30, 2003 to Hill, M. et al.;
175. U.S. Patent No. 6,668,191 issued December 23, 2003 to Boveja, B.;
176. U.S. Patent No. 6,671,556 issued December 30, 2003 to Osorio, I. et al.;
177. U.S. Patent No. 6,684,105 issued January 27, 2004 to Cohen, E.;
178. U.S. Patent No. 6,865,416 issued March 8, 2005 to Dev, N. et al.;
179. U.S. Patent No. 6,895,280 issued May 17, 2005 to Meadows, P. et al.;
180. U.S. Patent No. 6,907,295 issued June 14, 2005 to Gross, Y. et al.;

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183. U.S. Patent No. 6,985,774 issued January 10, 2006 to Kieval, R. et al.;
184. U.S. Patent No. 7,050,846 issued May 23, 2006 to Sweeney, R. et al.;
185. U.S. Patent No. 7,076,299 issued July 11, 2006 to Thong, T.;
186. U.S. Statutory Invention Registration No. H1,905, published October 3, 2000 (Hill);
187. Waninger, M.S. et al., (2000) "Electrophysiological Control Of Ventricular Rate During Atrial Fibrillation," *Pacing and Clinical Physiology*, 23(8): 1236-44 (**Exhibit 27**); and
188. Zhang, Y. et al., (2002) "Optimal Ventricular Rate Slowing During Atrial Fibrillation By Feedback AV Nodal-Selective Vagal Stimulation," *American Journal of Physiology: Heart and Circulatory Physiology*, 282(3): H1102-10 (**Exhibit 28**);

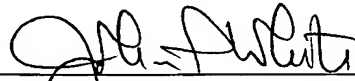
Copies of documents numbers 1-26 and 187-188 are attached hereto as **Exhibits 1-26** and **27-28**, respectively. In accordance with 37 C.F.R. §1.92(a)(2)(ii), copies of U.S. Patents and U.S. Patent Application Publications need not be provided. Accordingly, a

Applicants: Omry Ben-Ezra, et al.
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Page 20

copy of documents listed above as items 27-186 are not submitted herewith.

No fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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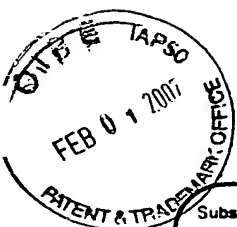
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1/29/07

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Reg. No. 28,678

Date



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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

Application Number	10/560,654
Filing Date	1 May 2006
First Named Inventor	Omry Ben-Ezra
Art Unit	3762
Examiner Name	
Attorney Docket Number	75632/JPW/YC

Sheet 1 of 12

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	1	Bibevski, S. and Dunlap M.E., (1999) "Ganglionic Mechanisms Contribute To Diminished Vagal Control In Heart Failure," Circulation, 99(22):2958-63	
	2	Bogutsky, A.M. et al., (1968) "Vagal Tuning, A New Concept In The Treatment Of Supraventricular Arrhythmias, Angina Pectoris, And Heart Failure," The Journal of Thoracic and Cardiovascular Surgery, 56(1): 71-82	
	3	Bluemel, K.M. et al., (1990) "Parasympathetic Postganglionic Pathways To the Sinoatrial Node," The American Journal of Physiology, 259(5 Pt 2):H1504-10	
	4	Carlson, M.D. et al., (1992) "Selective Stimulation Of Parasympathetic Nerve Fibers To The Human Sinoatrial Node," Circulation, 85: 1311-1317	
	5	Chen, S. et al., (1998) "Intracardiac Stimulation Of Human Parasympathetic Nerve Fibers Induces Negative Dromotropic Effects: Implication With The Lesions Of Radiofrequency Catheter Ablation," Journal of Cardiovascular Electrophysiology, 9(3): 245-52	
	6	Cooper, T.B. et al., (1980) "Neural Effects On Sinus Rate And Atrioventricular Conduction Produced By Electrical Stimulation From A Transvenous Electrode Catheter In The Canine Right Pulmonary Artery," Circulation Research, 46: 48-57	
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	10	Friedrichs, G., (2000) "Experimental Models Of Atrial Fibrillation/Flutter," Journal of Pharmacological and Toxicological Methods, 43: 117-123	
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Examiner Signature	Date Considered
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Applicants: Omry Ben-Ezra, et al.
U.S. Serial No. 10/560,654
Filed: May 1, 2006
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Complete if Known

Application Number	10/560,654
Filing Date	1 May 2006
First Named Inventor	Omy Ben-Ezra
Art Unit	3782
Examiner Name	
Attorney Docket Number	75632/JPW/YC

Sheet

2

of

12

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
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	25	Page, P.L. et al., (1995) "Regional Distribution Of Atrial Electrical Changes Induced By Stimulation Of Extracardiac And Intracardiac Neural Elements," <i>The Journal of Thoracic and Cardiovascular Surgery</i> , 109(2): 377-88	
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Sheet 3

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10/560-6-54

1 May 2006

Omry Ben-Ezra

3762

75632/JPW/YC

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 4 of 12**Complete if Known**

Application Number	10/560,654
Filing Date	1 May 2006
First Named Inventor	Omy Ben-Ezra
Art Unit	3762
Examiner Name	
Attorney Docket Number	75632/JPW/YC

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
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	28	US- 2002-0107553	08-08-2002	Hill, M. et al.	
	29	US- 2002-0120304	08-29-2002	Mest, R.	
	30	US- 2003-0018367	01-23-2003	Diorenzo, D.	
	31	US- 2003-0040774	09-16-2003	Terry, R. et al.	
	32	US- 2003-0045909	03-06-2003	Gross, Y. et al.	
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Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
	8	EP 0 688 577	12-27-1995	PACESETTER AB		
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	19	WO 02-085448	10-31-2002	UNIV OKLAHOMA STATE		

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Complete if Known

Application Number	10/560,654
Filing Date	1 May 2006
First Named Inventor	Omry Ben-Ezra
Art Unit	3762
Examiner Name	
Attorney Docket Number	75632/TPH/YC

Sheet 15 of 12

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	46	US- 2004-0162594	08-19-2004	King, G.	
	47	US- 2004-0172075	09-02-2004	Shafer, L. et al.	
	48	US- 2004-0199210	10-07-2004	Sheichuk, A.	
	49	US- 2004-0215289	11-28-2006	Fukui, Y.	
	50	US- 2004-0243182	12-02-2004	Cohed, E. et al.	
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	52	US- 2005-0131467	06-16-2005	Bojeva, B.	
	53	US- 2005-0187584	08-25-2005	Denker, S. et al.	
	54	US- 2005-0222644	10-06-2005	Killen, M. et al.	
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	56	US- 2006-0052831	03-09-2006	Fukui, Y.	
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Application Number	10/560,654
Filing Date	1 May 2006
First Named Inventor	Omry Ben-Ezra
Art Unit	3762
Examiner Name	
Attorney Docket Number	75632/JPH/YC

Sheet 6 of 12

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	65	US- 4,535,785	08-20-1985	Honert, C.V.D.	
	66	US- 4,559,948	12-24-1985	Lisa, S. et al.	
	67	US- 4,573,481	03-04-1986	Bullara, L.A.	
	68	US- 4,585,005	04-29-1986	Lue, T.F. et al.	
	69	US- 4,602,624	07-29-1986	Naples, G.G. et al.	
	70	US- 4,608,985	09-02-1986	Crish, T.J. et al.	
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	73	US- 4,649,936	04-17-1987	Ungar, I.J. et al.	
	74	US- 4,663,102	05-05-1987	Brennan, H.S. et al.	
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	77	US- 4,867,164	09-19-1989	Zabara, J.	
	78	US- 4,926,865	05-22-1990	Oman, P.S.	
	79	US- 4,962,751	10-16-1990	Krauter, A.I.	
	80	US- 5,025,807	06-25-1991	Zabara, J.	
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FOREIGN PATENT DOCUMENTS

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**INFORMATION DISCLOSURE
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Sheet 7 of 12**Complete if Known**

Application Number	10/560,654
Filing Date	1 May 2006
First Named Inventor	Omry Ben-Ezra
Art Unit	3762
Examiner Name	
Attorney Docket Number	75632/JPW/YC

U. S. PATENT DOCUMENTS					
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		Number-Kind Code ² (if known)			
	84	US- 5,178,161	01-12-1993	Kovacs, G.T.A.	
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	90	US- 5,215,088	06-01-1993	Terry, R.S. et al.	
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	93	US- 5,263,480	11-23-1993	Wernicke, J.F. et al.	
	94	US- 5,282,468	02-01-1994	Klepinski, R.J.	
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	100	US- 5,335,657	08-09-1994	Terry, R.S. et al.	
	101	US- 5,358,425	10-18-1994	Bardy, G.H. et al.	
	102	US- 5,411,531	05-02-1995	Hill, M.R.S. et al.	

FOREIGN PATENT DOCUMENTS					
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet **8** of **12****Complete if Known**

Application Number	10/560,654
Filing Date	1 May 2006
First Named Inventor	Omry Ben-Ezra
Art Unit	3762
Examiner Name	
Attorney Docket Number	75632/JPW/YC

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	104	US- 5,437,285	08-01-1995	Venier, R.L. et al.	
	105	US- 5,437,285	08-08-1995	Snyder, S.H. et al.	
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	107	US- 5,487,756	01-30-1996	Kallosco, K.	
	108	US- 5,507,784	04-16-1996	Hill, M.R.S. et al.	
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	113	US- 5,571,150	10-05-1996	Wernicke, J.F. et al.	
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Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear
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STATEMENT BY APPLICANT**

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Sheet **19** of **12****Complete if Known**

Application Number	10/560,654
Filing Date	1 May 2006
First Named Inventor	Omry Ben-Ezra
Art Unit	3762
Examiner Name	
Attorney Docket Number	75632/JPW/YC

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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	127	US- 5,833,703	11-10-1998	Rise, M.T. et al.	
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	131	US- 6,006,134	12-21-1999	Hill, M.R.S. et al.	
	132	US- 6,026,326	02-15-2000	Bardy, G. H.	
	133	US- 6,058,331	05-02-2000	King, G.W. et al.	
	134	US- 6,066,163	05-23-2000	John, M.S.	
	135	US- 6,073,048	08-08-2000	Kieval, R.S. et al.	
	136	US- 6,086,525	07-11-2000	Davey, K.R. et al.	
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Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁴
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Sheet 10

of 12

Application Number	10/560,654
Filing Date	1 May 2006
First Named Inventor	Omyr Ben-Ezra
Art Unit	3762
Examiner Name	
Attorney Docket Number	75632/JPW/YC

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Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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Application Number **10/560,654**
 Filing Date **1 May 2006**
 First Named Inventor **Omry Ben-Ezra**
 Art Unit **3762**
 Examiner Name
 Attorney Docket Number **75632/JPW/YC**

Sheet **11** of **12****U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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	165	US- 6,463,328	10-08-2002	John, M.S.	
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	172	US- 6,600,956	07-29-2003	Maschino, S. et al.	
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Sheet 12

of 12

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Application Number	10/560-654
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Filing Date	1 May 2006
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First Named Inventor	Omer Ben-Ezra
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Art Unit	3762
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Examiner Name

Attorney Docket Number	75632/JPW/YC
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